UNITED STATES DISTRICT COURT FOR WESTERN DISTRICT OF MICHIGAN SOUTHERN DIVISION

RENEE CARLSON and GREGORY CARLSON,	)	**Case No.:** 1:21-cv-502
Plaintiffs,	)	**COMPLAINT**
v.	)	
DAVOL, INC., C.R. BARD, INC., ETHICON, INC. AND JOHNSON & JOHNSON,	)	**JURY TRIAL DEMANDED**
Defendants.	)	

COMPLAINT

Plaintiffs, Renee Carlson and Gregory Carlson (hereinafter "Plaintiffs"), by and through their undersigned counsel, bring this Complaint for damages against Ethicon, Inc. ("Ethicon"), and Johnson & Johnson ("J&J"), (collectively "Ethicon Defendants") and C.R. Bard, Inc. ("Bard") and Davol, Inc. ("Davol"), (collectively "Bard Defendants") and, in support thereof, state the following:

1. This is a medical device tort action brought on behalf of the above-named Plaintiffs arising out of the failure of Defendants' hernia mesh product, the Ethicon Prolene Hernia System ("PHS") and the Bard 3D Max ("3D Max") (collectively known as "Mesh Products"). As a result, Plaintiffs have suffered permanent injuries and significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life.

Plaintiffs respectfully seek damages in excess of $75,000 for all damages to which they may be legally entitled.

STATEMENT OF PARTIES

2. At all material times Plaintiffs have been citizens and residents of Lowell, Michigan and the United States.

3. Davol, Inc. ("Davol") is incorporated in Delaware, with its principal place of business in Rhode Island. Davol is a medical device company involved in the research, development, testing, manufacture, production, marketing, promotion and/or sale of medical devices. Such devices include hernia meshes composed of small pore, heavyweight polypropylene such as the 3D Max. Davol has its principal place of business in the State of Rhode Island. It manufactures the 3D Max mesh device and is located at 100 Crossings Boulevard, Warwick, Rhode Island. Davol has a registered agent in Rhode Island at CT Corporation System, 450 Veterans Memorial Parkway, Suite 7A, East Providence, Rhode Island. Davol focuses its business on products in key surgical specialties, including hernia repair, hemostasis, orthopedics, and laparoscopy.

4. Defendant C. R. BARD INC. (*hereinafter* "BARD") is a corporation that is incorporated under the laws of the State of New Jersey. Bard's principal place of business is located at 730 Central Avenue, Murray Hill, New Jersey, 07974. It is the corporate parent/stockholder of Davol and participates in the manufacture and distribution of the 3D Max. It also manufactures and supplies Davol with material that forms part of the 3D Max Bard. At all times relevant, Bard did substantial and continuous business in the State of Michigan.

5. Bard was at all times relevant responsible for the actions of Davol, and exercised control over Davol's functions specific to the oversight of and compliance with applicable safety

standards relating to and including 3D Max sold in the United States. In such capacity, Bard committed or allowed to be committed tortious and wrongful acts, including the violation of numerous safety standards relating to device manufacturing, quality assurance/control, and conformance with design and manufacturing specifications. Bard's misfeasance and malfeasance caused Plaintiffs to suffer injury and damages

6. Defendant Johnson & Johnson ("J&J") is a corporation incorporated under the laws of New Jersey with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey. All acts and omissions of J&J as described herein were done by its agents, servants, employees, and/or owners, acting in the course and scope of their respective agencies, services, employments, and/or ownership. J&J is a manufacturer of medical devices, diagnostics and consumer products related to healthcare, health, beauty products, and medical devices. J&J's misfeasance and malfeasance caused Plaintiff to suffer injury and damages.

7. Defendant J&J organizes its subsidiary businesses into individual Business Units, which coordinate the development, manufacture, testing, marketing, promoting, training, distribution, and sale of J&J products, including its hernia repair mesh devices such as the Proceed at issue here. The corporate structure of J&J contains three sectors: (1) medical devices and diagnostics; (2) pharmaceutical; and (3) consumer.

8. Within the medical devices and diagnostic sector are "Business Units" as well, including the "Ethicon Franchise". J&J charged the Ethicon Franchise with the design, development, promotion, marketing, testing, training, distribution and sale of the Proceed, the hernia repair device that was implanted in Plaintiff.

9. Gary Pruden, the Company Group Chairman and Worldwide Franchise Chairman for the Ethicon Franchise, is a J&J employee. The companies comprising the Ethicon Franchise are thus controlled by Defendant J&J, and include Defendant Ethicon, Inc.

10. Defendant Ethicon, Inc. ("Ethicon") is a corporation incorporated under the laws of New Jersey with its principal place of business in Sommerville, New Jersey. It is a wholly owned subsidiary of Defendant J&J. All acts and omissions of Ethicon as described herein were done by its agents, servants, employees, and/or owners, acting in the course and scope of their respective agencies, services, employments, and/or ownership. Ethicon is a medical device company involved in the research, development, testing, manufacture, production, marketing, promotion and/or sale of medical devices, including the PHS, which is an Ethicon Multi-Layered Hernia Mesh. Ethicon's secondary corporate headquarters is located in Cincinnati, Ohio. Ethicon's misfeasance and malfeasance caused Plaintiff Renee Carlson to suffer injury and damages.

11. "C.R. Bard" and "Davol" are collectively hereinafter referred to as the "Bard Defendants".

12. "J&J" and "Ethicon" are collectively hereinafter referred to as the "Ethicon Defendants".

13. C.R. Bard, Davol, J&J, and Ethicon are hereinafter collectively referred to as "Defendants".

14. Defendants are individually, jointly and severally liable to Plaintiffs for damages suffered by Plaintiffs arising from the Defendants' design, manufacture, marketing, labeling, distribution, sale and placement of its defective Mesh Products at issue in the instant suit, effectuated directly and indirectly through their respective agents, servants, employees and/or

owners, all acting within the course and scope of their representative agencies, services, employments and/or ownership.

15. Defendants are vicariously liable for the acts and/or omissions of their employees and/or agents who were at all times relevant hereto acting on behalf of Defendants and within the scope of their employment or agency with Defendants.

VENUE AND JURISDICTION

16. At all material times, Plaintiffs have been citizens and residents of Lowell, Michigan and the United States.

17. This Court has subject-matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(a) based on complete diversity of citizenship between Plaintiffs and all Defendants. The amount in controversy exceeds $75,000.00.

18. This Court has personal jurisdiction over each of the Defendants pursuant to the Michigan Long-Arm Statute, Mich. Comp. Laws § 600.715. Defendants transact business within the State of Michigan, and contracted to sell and supply their Mesh Products in the State of Michigan. Defendants employ sales representatives in the State of Michigan to sell their products throughout the State, including the Mesh Products similar to those implanted in Plaintiff Renee Carlson in the State of Michigan. Defendants' tortious acts and omissions in the State of Michigan caused injury to Plaintiff Renee Carlson.

19. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because the events or omissions giving rise to Plaintiffs' claims occurred in this district.

20. Venue is proper in this Court pursuant to 28 U.S.C. § 1332 by virtue of the fact that (a) a substantial part of the events or omissions giving rise to the claims occurred in this District and (b) Defendants' products are sold to and consumed by individuals in the State of

Michigan, thereby subjecting Defendants to personal jurisdiction in this action and making them all "residents" of this judicial District.

21. Defendants have purposefully engaged in Michigan in the business of developing, manufacturing, publishing information, marketing, distributing, promoting and/or selling, either directly or indirectly, through third parties or other related entities, medical devices including the Mesh Products, for which they derived significant and regular income. Defendants have conducted, and continue to conduct, substantial business in the State of Michigan and in this District; distribute the Mesh Products in this District; receive substantial compensation and profits from sales of Mesh Products in this District; and make material omissions and misrepresentations and breaches of warranties in this District, so as to subject them to personal jurisdiction in this District.

3D MAX FACTS

66. The 3D Max was designed and is manufactured and distributed by Bard and its subsidiary, Davol, who owns the patent on the device that was inserted into Plaintiff Renee Carlson's body.

67. Defendants designed, manufactured and distributed the 3D Max that was inserted into Plaintiff Renee Carlson's body.

68. Defendants, through its agents, servants, and employees, participated in the manufacture and delivery of the 3D Max that was inserted into Renee Carlson's body.

69. Defendants sought and obtained Federal Drug Administration (*hereinafter* "FDA") clearance to market their hernia mesh devices, including the 3D Max, under Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act. Section 510(k) provides for marketing of a medical device if the device is deemed "substantially equivalent" to

other predicate devices marketed prior to May 28, 1976. No clinical testing or clinical study is required to gain FDA clearance under this process. Upon information and belief, no formal review of safety or efficacy was ever conducted for the hernia mesh devices, including the 3D Max.

70. 3D Max is a small pore, heavyweight polypropylene, three-dimensional concave mesh marketed by Defendants as a mesh to be used in repairing hernias and to provide extra reinforcement to the hernia defect.

71. Defendants' 3D Max product contains heavyweight polypropylene. Despite claims that this material is inert, a substantial body of scientific evidence shows that this mesh material is biologically incompatible with human tissue and promotes an immune response in a large subset of the population receiving these products. This immune response promotes degradation of the polypropylene mesh, as well as the surrounding tissue, and can contribute to the formation of severe adverse reactions to the mesh.

72. Defendants' statements made to the FDA regarding these devices inadequately relied on predicate devices and not clinical testing or other design verification testing. These statements induced her implanting surgeon and Plaintiff Renee Carlson into relying upon Defendants' judgment.

73. 3D Max is designed, indicated, and utilized for permanent implantation in the human body in the groin area.

74. Upon information and belief, Defendants' numerous suppliers, of various forms of polypropylene, cautioned all users in their United States Material Safety Data Sheet ("MSDS") that the polypropylene was not to be used for medical applications involving

permanent implantation in the human body or permanent contact with internal body fluids or tissues.

75. Defendants failed to warn or notify doctors, regulatory agencies, and consumers of the severe and life-threatening risks associated with polypropylene.

76. The polypropylene used in the manufacture the 3D Max, which was implanted into Plaintiff Renee Carlson, is not suited for implantation into the human body due to its small pore size and weave, high volume of material utilized, selection of polypropylene resin, and other design features. These design aspects lead to adverse tissue reactions in the body, which directly lead to complications.

77. The 3D Max is comprised of heavyweight, small pore polypropylene, which increases inflammation, foreign body response, and subsequent complications.

78. The 3D Max implanted in Plaintiff Renee Carlson was designed, manufactured, sold and distributed by Defendants to be used by surgeons for hernia repair surgeries and was further represented by Defendants to be an appropriate, cost-effective and suitable product for such purpose.

79. Defendants knew or should have known that the Hernia Mesh Devices implanted in the groin will be subject to movement and bending. Polypropylene in the groin has a higher likelihood of folding and bunching, and the scar fills the spaces between the folds. The phenomenon was termed a “meshoma” because the mesh forms a tumor-like mass.

80. A malfunction of this device can lead to nerve damage and chronic pain as well as other chronic and debilitating conditions.

81. Upon information and belief, Defendants were and are aware of the defects in the manufacture and design of the 3D Max and chose, and continue to choose, not to issue a recall of

these products, including the 3D Max implanted in the Plaintiff Renee Carlson, in the face of a high degree of complication and failure rates.

82. Plaintiff Renee Carlson has suffered and will continue to suffer physical pain as well as mental anguish and emotional distress.

83. Plaintiff Renee Carlson has also incurred substantial medical bills and has suffered loss of other monies due to the defective hernia patch that was implanted in his body.

84. Plaintiff Renee Carlson also requires further medical treatment, including likely need for future surgeries.

PROLENE HERNIA SYSTEM FACTS

41. Defendant J&J is a corporation incorporated under the laws of New Jersey with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey. J&J charged the Ethicon Franchise with the design, development, promotion, marketing, testing, training, distribution and sale of the Prolene Hernia System.

42. Defendant Ethicon is a corporation incorporated under the laws of New Jersey with its principal place of business in Sommerville, New Jersey. It is a wholly owned subsidiary of Defendant J&J. Ethicon is a medical device company involved in the research, development, testing, manufacture, production, marketing, promotion and/or sale of medical devices, including the Prolene Hernia System.

43. The PHS was designed, manufactured and distributed by Defendants, who own the patent on this devices that was inserted into Plaintiff Renee Carlson's body.

44. Defendants designed, manufactured and distributed the PHS that was inserted into Plaintiff Renee Carlson's body.

45. Defendants, through its agents, servants, and employees, participated in the

manufacture and delivery of the PHS that was inserted into Plaintiff Renee Carlson's body.

46. At all relevant times, Defendants held themselves out to the public as being knowledgeable, skilled and experienced in the design, manufacture, production, assembly, distribution and sale of medical devices used for hernia repair, including the polypropylene PHS at issue.

47. Prolene Hernia System did not undergo premarket approval, but instead received 510(k) clearance on or about September 20, 1997. The Prolene Hernia System was initially approved for the intended use of repairing "indirect and direct inguinal hernia defects." However, in the Instructions for Use for the Prolene Hernia System, Defendants market the Prolene Hernia System as "indicated for the repair of inguinal (direct & indirect) and abdominal wall hernia defects."

48. Prolene Hernia System has a unique design, which incorporates two distinct layers of polypropylene connected by a central polypropylene tube. This design is not used in any other hernia repair product sold in the United States.

49. Although Defendants represented and warranted the multi-layer polypropylene design to prevent or minimize hernia recurrence and chronic pain, the design did not do so. Instead, the multi-layer polypropylene mesh occupied two inguinal compartments instead of one, increasing the intense inflammatory and chronic foreign body response, which resulted in mesh stiffening, mesh hardening, mesh contracture, mesh deformation, mesh migration, granulomatous and/or fibrotic tissue, increased foreign body sensation, and increased chronic and debilitating pain.

50. When an implanted Prolene Hernia System fails, the complications are harder to treat. Further, its eventual explantation results in large amounts of tissue loss due to the Prolene

Hernia System's occupying of two inguinal compartments.

51. The polypropylene mesh material for the Ethicon Multi-Layered Hernia Mesh, used in the Prolene Hernia System, is unreasonably susceptible to in vivo oxidative degradation. Such degradation causes or exacerbates excessive inflammation and adverse foreign body reaction, leading to shrinkage, scarification, pain, and mesh deformation.

52. In 2018, the HerniaSurge Group published *International Guidelines for Groin Hernia Management*. The Guidelines were endorsed by the European Hernia Society, Americas Hernia Society, Asia Pacific Hernia Society, Afro Middle East Hernia Society, Australasian Hernia Society, International Endo Hernia Society, and European Associated for Endoscopic Surgery and Other Interventional Techniques. The HerniaSurge Group's Guidelines note the following: "three dimensional implants (plug-and-patch and bilayer) are not recommended because of the excessive use of foreign material, the need to enter both the anterior and posterior planes and the additional cost.

53. Before placing Ethicon Multi-Layered Hernia Mesh, or any hernia repair device using it, on the market, Defendants were required to adequately test their product and mitigate its risks, including any design element which could cause the following: render the device ineffective, weaken the structural integrity of the device, prevent safe treatment when complications arise, increase complications, or increase or prolong inflammation after implantation. Such complications can result in an increase in adhesion formation, mesh shrinkage, mesh deformation, pain, organ complications, hernia recurrence, and/or the need for early surgical revision in patients/consumers.

54. Defendants designed, manufactured, promoted, marketed and sold Ethicon Multi-Layered Hernia Mesh, despite their long-standing knowledge that their material and design

would cause dense adhesions, chronic pain, mesh shrinkage, mesh deformation, foreign body sensation, organ complications, and hernia recurrence. Further, Defendants knew that treating such complications when they inevitably arose would result in even greater complications and a larger defect.

55. Defendants marketed Ethicon Multi-Layered Hernia Mesh, such as the Prolene Hernia System at issue here, to health care professionals, hospitals, and group purchasing organizations (GPOs).

56. Defendants had the ability to inform the above purchasers of developing problems or defects related to those products through varied communications, such as e-mails, letters, recalls, warnings in product inserts, and/or through product representatives who communicate, interact and work with surgeons, but failed to do so.

57. The multiple layers of Ethicon Multi-Layered Hernia Mesh increase the intensity and duration of the inflammatory response in Defendants' hernia repair devices, including their Prolene Hernia System. That response in turn increases dense adhesion formation from underlying structures and organs to the product, resulting in mesh contracture, mesh deformation, nerve entrapment, nerve damage, chronic pain, foreign body sensation, foreign body reaction, organ and tissue damage, hernia recurrence and more.

58. The Prolene Hernia System IFU has a section for adverse reactions, which list "Potential adverse reactions are those typically associated with surgically implantable materials…" The polypropylene of the Prolene Hernia System carries many potential adverse reactions, such as a life-long inflammatory response that other surgically implantable materials do not present. Additionally, the multiple layers of the Prolene Hernia System further increase the inflammatory response and rate of infection, adhesion formation, chronic pain, seroma

formation, fistula formation, hematomas, mesh contracture, nerve entrapment, nerve damage, hernia recurrence, mesh migration, bowel complications, foreign body response, extrusion, and other additional injuries.

59. There is not a contraindication section in the Prolene Hernia System IFU.

60. Defendants never performed any clinical trials and/or studies before marketing Ethicon Multi-Layered Hernia Mesh, including the Prolene Hernia System.

61. Defendants did not fully and/or adequately test these new, multi-layered hernia mesh devices, one of which—the Prolene Hernia System—was implanted in Plaintiff Renee Carlson.

62. Reassurances of device safety were made through direct promotional contact by Defendants' sales representatives and distributors, through word-of-mouth from their physician/technical consultants, and/or through industry-targeted promotional materials.

63. Despite these reassurances, the defective design and manufacture of the Ethicon Multi-Layered Hernia Mesh, including Defendants' Prolene Hernia System, continued to elicit post-implant severe and chronic inflammatory responses. Such responses resulted in mesh contracture, mesh deformation, nerve damage, chronic pain, foreign body sensation, adhesion, seroma and fistula formation, organ injuries, hernia recurrence, infections, erosion, extrusion, and additional complications.

64. From the time Defendants first began selling Ethicon Multi-Layered Hernia Mesh in the U.S. through the present, their product labeling and product data have failed to contain adequate information, instructions, and warnings concerning the following: implantation of the mesh, explantation of the mesh, propensity of the mesh to massively shrink and change shape, the increased duration and intensity of inflammation, and the elevated rate of adhesions, organ

complications, chronic and debilitating pain, foreign body sensation, hernia recurrence, nerve entrapment, nerve damage, seroma, hematoma and fistula formation, erosion, extrusion, infection, and other injuries occurring at a higher rate than other surgically implanted devices.

FACTS COMMON TO ALL COUNTS

65. Plaintiffs are citizens and residents of Lowell, Michigan and the United States.

66. Defendant Davol is a corporation that is incorporated under the laws of the State of Delaware. Davol has its principal place of business in the State of Rhode Island. It manufactures the Composix and is located at 100 Crossings Boulevard, Warwick, Rhode Island. Davol focuses its business on products in key surgical specialties, including hernia repair, hemostasis, orthopedics, and laparoscopy.

67. Defendant Bard is a corporation that is incorporated under the laws of the State of New Jersey. It is the corporate parent/stockholder of Davol and participates in the manufacture and distribution of the 3D Max. It also manufactures and supplies Davol with material that forms part of the 3D Max.

68. Defendant J&J is a corporation incorporated under the laws of New Jersey with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey. J&J charged the Ethicon Franchise with the design, development, promotion, marketing, testing, training, distribution and sale of the PHS.

69. Defendant Ethicon is a corporation incorporated under the laws of New Jersey with its principal place of business in Sommerville, New Jersey. It is a wholly owned subsidiary of Defendant J&J. Ethicon is a medical device company involved in the research, development,

testing, manufacture, production, marketing, promotion and/or sale of medical devices, including the PHS.

70. Upon information and belief, at all relevant times, Defendants transacted, solicited, and conducted business in the State of Michigan and derived substantial revenue from such business.

71. The Mesh Products were designed, manufactured and distributed by Defendants who own the patent on their respective devices that were inserted into Plaintiff Renee Carlson's body.

72. Defendants designed, manufactured and distributed the Mesh Products that were inserted into Plaintiff Renee Carlson's body.

73. Defendants, through its agents, servants, and employees, participated in the manufacture and delivery of the Mesh Products that were inserted into Plaintiff Renee Carlson's body.

74. At all relevant times, Defendants held themselves out to the public as being knowledgeable, skilled and experienced in the design, manufacture, production, assembly, distribution and sale of medical devices used for hernia repair, including the polypropylene Mesh Products at issue.

75. Defendants had the requisite knowledge, skill and expertise to know that implanted devices, such as polypropylene mesh, must be chemically inert, non-carcinogenic, and able to withstand mechanical stress. Implanted devices, such as polypropylene mesh, must also not be physically modified by tissue fluids, not allow tissue infiltration, not incite an inflammatory or foreign body cell reaction, and not produce allergic reactions.

76. Polypropylene is not biologically inert in the human body, as it is known to expand as well as shrink, and can cause serious injury to patients, significantly impacting their quality of life.

77. Moreover, it is well known within the scientific and medical community that the polypropylene used for surgical treatment begins to degrade after implantation in the human body, which can lead to infection and irritation, and result in serious pain as the body tries to rid itself of the foreign material.

78. Scientific literature regarding the safety and effectiveness of these devices suggests that polypropylene mesh repair does not improve symptomatic results or quality of life over traditional non-mesh repair.

79. Defendants were fully aware of the dangers the defective products they were placing into the stream of commerce posed to their customers, specifically the polypropylene Mesh Products, which have been shown to pose an unreasonable risk of human body inflammation, granuloma formation, foreign body reaction, excessive scar tissue formation and long-term complications.

80. Despite the abundance of scientific and medical information available relating to the dangerous properties and serious risks of the Mesh Products, Defendants deliberately ignored these dangers and aggressively promoted the Mesh Products polypropylene mesh to healthcare providers and/or directly to consumers.

81. Defendants expressly warranted that the polypropylene Mesh Products were safe and fit for use by consumers, that they were of merchantable quality, and they were adequately tested and fit for its intended use, even though they were not safe and had numerous side effects, many of which Defendants did not accurately warn about.

82. The Mesh Products, with their unusual design, were nothing more than marketing ploys to capture the revenue stream from the lucrative hernia mesh market.

83. Defendants designed, developed, manufactured, assembled, distributed, tested, marketed, promoted and/or sold to the public, including Plaintiff Renee Carlson, for profit, the at issue polypropylene Mesh Products in a defective condition such that the polypropylene Mesh Products failed and had to be surgically removed after numerous complications arose.

84. The Mesh Products that were implanted in Plaintiff Renee Carlson were designed, manufactured, sold and distributed by Defendants to be used by surgeons for hernia repair surgeries and were further represented by Defendants to be an appropriate, cost-effective and suitable products for such purpose.

85. The polypropylene mesh used in the manufacture of the Mesh Products, which were implanted into Plaintiff Renee Carlson, are unreasonably dangerous, defective, and negligently designed in the following ways:

(a) The weave of the mesh produces very small interstices which allow bacteria to enter and hide from the host defenses designed to eliminate them. The bacteria can secrete an encasing slime (biofilm) which further serves to protect them from destruction by white blood cells and macrophages.

(b) Polypropylene is impure: there is no such thing as pure polypropylene (PP). PP contains about 15 additional compounds which are leached from the PP and are toxic to tissue which enhances the inflammatory reaction and the intensity of fibrosis.

(c) Mesh was shown to be not inert in 2003 with flaking and fissuring demonstrated by scanning electron microscopy which leads to degradation and

release of toxic compounds. This enhances the inflammatory and fibrotic reactions.

(d) With loss of PP due to degradation, the surface area is greatly increased, thus providing greater areas for bacterial adherence and more elution of toxic compounds from the PP, and also the freed toxic PP itself, all of which increases the inflammatory reaction and intensity of fibrosis.

(e) By 1998 polypropylene mesh was known to shrink 30-50%.

(f) Heat begins the process of degradation.

(g) Predominate infection/inflammation was noted at least in 2007 in explanted samples.

(h) Allergic reactions occur with polypropylene after implantation.

(i) Polypropylene is subject to oxidation by acids produced during the inflammatory reaction which caused degradation and loss of compliance.

(j) Mesh porosity is important for tissue ingrowth, with low porosity decreasing tissue incorporation. Porosity also affects the inflammatory and fibrotic reaction. With mechanical stress the porosity of the pores is decreased.

(k) Observation of mesh under the scanning electron microscope reveals that very small interstices exist between the mesh fibrils, which are too small for a macrophage to enter to destroy incubating bacteria. Some bacteria are capable of degrading polypropylene.

(l) Polypropylene is known to depolymerize, cross-link, undergo oxidative degradation by free radicals, and stress crack after implantation in the human body.

(m) Polypropylene migrates to lymph nodes when there is a foreign body giant cell reaction.

(n) The large surface area promotes wicking of fluids and bacteria and is a "bacterial super highway" which provides a safe haven for bacteria.

(o) Common complications associated with PP include restriction of abdominal wall mobility and local wound disturbances. Often failures of PP include persistent and active inflammatory processes, irregular or low formation of scar tissue and unsatisfying integration of the mesh in the regenerative tissue area.

(p) Klosterhalfen published a series of 623 explanted mesh samples removed for pain, infection and recurrence. There are also reports of mesh migration and erosion into the sigmoid colon. Reduced mobility of the abdominal wall has also been found. Moreover, the rate of chronic pain after mesh hernia repair ranges from 4-40%. Thus, Defendants should have been aware of these issues with polypropylene.

86. A malfunction of the devices can lead to chronic pain, nerve entrapment and nerve damage as well as other chronic and debilitating conditions.

87. Upon information and belief Defendants failed to comply with the FDA application and reporting requirements.

88. Upon information and belief Defendants were aware of the high degree of complication and failure rate associated with the Mesh Products.

89. Upon information and belief Defendants were aware of the defects in the manufacture and design of the Mesh Products.

90. Upon information and belief, Defendants manipulated, altered, skewed, slanted, misrepresented, and/or falsified pre-clinical and/or clinical studies to bolster the perceived performance of the Mesh Products.

91. Upon information and belief, Defendants paid doctors, surgeons, physicians, and/or clinicians to promote the Mesh Products but did not readily disclose this information.

92. Defendants failed to properly investigate and disclose adverse event reports to the FDA and other regulatory agencies worldwide.

93. Defendants failed to implement adequate procedures and systems to report, track, and evaluate complaints and adverse events.

94. Defendants marketed the Mesh Products to the medical community and to patients as safe, effective, reliable, medical devices for the treatment of hernia repair, and as safer and more effective as compared to the traditional products and procedures for treatment, and other competing mesh products. Defendants did not undergo pre-market approval for the Mesh Products and are, therefore, prohibited by the FDA from asserting superiority claims.

95. Defendants failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Mesh Products.

96. Defendants failed to design and establish a safe, effective procedure for removal of the Mesh Products; therefore, in the event of a failure, injury, or complications it is difficult to safely remove the Mesh Products.

97. Defendants provided incomplete, insufficient, and misleading information to physicians in order to increase the number of physicians using the Mesh Products for the purpose of increasing their sales. By so doing, Defendants caused the dissemination of inadequate and misleading information to patients, including Plaintiff Renee Carlson.

98. The Mesh Products were utilized and implanted in a manner foreseeable to Defendants.

99. The Mesh Products that were implanted into Plaintiff Renee Carlson were in the same or substantially similar condition as when they left the possession of the Defendants, and in the condition directed by the Defendants.

100. On or about March 8, 2013, Plaintiff Renee Carlson underwent surgery for repair of a left groin hernia by Dr. Anthony Bozaan at the St. Joseph Mercy Livingston Hospital in Howell, Michigan. An Ethicon Prolene Hernia System mesh, Model No. PHSL and Lot No. 25288-05, was implanted to repair the hernia defect.

101. At the time of the operation, Plaintiff Renee Carlson was not informed of, and had no knowledge of the complaints, known complications and risks associated with the PHS.

102. Plaintiff Renee Carlson was never informed by the Ethicon Defendants of the defective and dangerous nature of the PHS.

103. At the time of the implant, neither Plaintiff Renee Carlson nor her physicians were aware of the defective and dangerous condition of the PHS.

104. On or about August 27, 2015, Plaintiff Renee Carlson underwent surgery for chronic pain, partial mesh removal and a recurrent left inguinal hernia by Dr. Jeffrey Gawel at Spectrum Health – Butterworth Campus in Grand Rapids, Michigan. The surgeon found that the previously implanted mesh plug was attached to the inferior epigastric vessels. Thus, only the portion of the mesh not attached to the vessels was removed. A Bard 3D Max, Model No. 0115310 and Lot No. HUYA0725, was implanted to repair the recurrent hernia defect.

105. At the time of the operation, Plaintiff Renee Carlson was not informed of, and had no knowledge of the complaints, known complications and risks associated with the 3D Max.

106. Plaintiff Renee Carlson was never informed by the Bard Defendants of the defective and dangerous nature of the 3D Max.

107. At the time of the implant, neither Plaintiff Renee Carlson nor her physicians were aware of the defective and dangerous condition of the 3D Max.

108. On or about June 15, 2018, Plaintiff Renee Carlson underwent an additional surgery by Dr. David Krpata at the Cleveland Clinic in Cleveland, Ohio. The surgeon performed a triple neurectomy of the left ilioinguinal, iliohypogastric and genitofemoral nerves. The surgeon also removed the left inguinal mesh except for a section that was left on the iliac artery as it was too high risk to remove it with the potential injury to that artery and iliac vein.

109. Plaintiff Renee Carlson has suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress.

110. Plaintiff Renee Carlson has also incurred substantial medical bills and has suffered loss of other monies due to the defective hernia patch that was implanted.

ESTOPPEL AND TOLLING OF STATUTE OF LIMITATIONS

111. Defendants are estopped from relying on any statutes of limitations or repose by virtue of their acts of fraudulent concealment, which include intentional concealment from Plaintiffs and/or the general public that the Mesh Products are defective, while continually marketing the products with the effects described in this Complaint.

112. Given Defendants' affirmative actions of concealment by failing to disclose this known but non-public information about the defects—information over which Defendants had exclusive control—and because Plaintiffs could not reasonably have known the Mesh Products were defective, Defendants are estopped from relying on any statutes of limitations that might otherwise be applicable to the claims asserted in this Complaint.

113. Despite diligent investigation by Plaintiff into the cause of Plaintiff Renee Carlson's injuries, including consultations with his medical providers, the nature of the injuries and damages, and their relationship to the Mesh Products were not discovered, and through reasonable care and diligence could not have been discovered until a date within the applicable statute of limitations for filing Plaintiff Renee Carlson's claims. Therefore, under appropriate application of the discovery rule, Plaintiff Renee Carlson's suit was filed well within the applicable statutory limitations period.

114. Further, in the existence of due diligence, Plaintiffs could not have reasonably discovered the Defendants' wrongful conduct, including, but not limited to, the defective design and/or manufacturing of the products until a date within the statute of limitations. Therefore, under appropriate application of the discovery rule, Plaintiffs' suit was filed well within the statutory limitations period.

COUNT I: STRICT LIABILITY – MANUFACTURING DEFECT

109. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs with the same force and effect as if more fully set forth herein.

110. Defendants expected and intended the Mesh Products to reach users such as Plaintiff Renee Carlson in the condition in which the products were sold.

111. The implantation of the Mesh Products in Plaintiff Renee Carlson's body was medically reasonable and was a type of use that Defendants intended and foresaw when they designed, manufactured and sold the products.

112. When the Mesh Products were implanted in Plaintiff Renee Carlson's body, they were defectively manufactured.

113. Defendants' poor quality control and general non-compliance resulted in the non-conformance of the Mesh Products implanted in Plaintiff Renee Carlson. The implanted product did not conform to Defendants' intended manufacturing and design specifications.

114. Upon information and belief, Defendants utilized substandard and adulterated polypropylene and raw materials used to make the Mesh Products, which deviated from Defendants' material and supply specifications.

115. As a direct and proximate result of the defective manufacture of the Mesh Products, Plaintiff Renee Carlson suffered injuries and damages as summarized in this Complaint including severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including obligations for medical services and expenses, impairment of personal relationships, and other damages.

116. Plaintiff Renee Carlson has suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress.

117. Plaintiff Renee Carlson has also incurred substantial medical bills and has suffered loss of other monies due to the Mesh Products that were implanted.

COUNT II: STRICT LIABILITY – DESIGN DEFECT

118. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs with the same force and effect as if more fully set forth herein.

119. The Mesh Products were defectively designed and/or manufactured and were not reasonably safe for their intended use in hernia repair; and the risks of the design outweighed any potential benefits associated with them. As a result of the defective design and/or manufacture of the Mesh Products, there was an unreasonable risk of severe adverse reactions to the meshes or

their components including: chronic infections; chronic pain; recurrence of hernia; foreign body response; rejection; infection; scarification; improper wound healing; excessive and chronic inflammation; allergic reaction; adhesions to internal organs; erosion; abscess; fistula formation; granulomatous response; seroma formation; nerve damage; tumor formation, cancer, tissue damage and/or death; and other complications.

120. When affixed to the body's tissue, the impermeable Mesh Products prevent fluid escape, which leads to seroma formation, and which in turn can cause infection or abscess formation and other complications.

121. The Mesh Products are defective in their design in part due to a material mismatch. This material mismatch results in the Mesh Products curling after implantation.

122. The design of the Mesh Products results in ineffective sterilization more often than flat single layer mesh.

123. The Mesh Products are cytotoxic, immunogenic, and not biocompatible, which causes or contributes to complications such as delayed wound healing, inflammation, foreign body response, rejection, infection, chronic pain and other complications.

124. These manufacturing and design defects associated with the product were directly and proximately related to the injuries Plaintiff suffered.

125. Neither Plaintiff Renee Carlson nor her implanting physician were adequately warned or informed by Defendants of the defective and dangerous nature of the products. Moreover, neither Plaintiff Renee Carlson nor her implanting physician were adequately warned or informed by Defendants of the risks associated with the Mesh Products.

126. The products implanted in Plaintiff Renee Carlson failed to reasonably perform as intended. They caused serious injury and had to be removed via invasive surgery and

necessitated additional invasive surgeries to repair the hernia that the products were initially implanted to treat.

127. When the Mesh Products were implanted in Plaintiff Renee Carlson's body, they were defectively designed. As described above, there was an unreasonable risk that the products would not perform safely and effectively for the purposes for which they were intended. Defendants failed to design against such dangers and failed to provide adequate warnings and instructions concerning the products' risks.

128. Defendants expected and intended the products to reach users such as Plaintiff Renee Carlson in the condition in which the products were sold.

129. The implantation of the Mesh Products in Plaintiff Renee Carlson's body was medically reasonable and was a type of use that Defendants intended and foresaw when they designed, manufactured and sold the products.

130. The risks of the products significantly outweigh any benefits that Defendants contend could be associated with it. Mesh Products incite an intense inflammatory response, leading to encapsulation, deformation, scarification and contraction, migration, erosion, rejection and chronic pain.

131. The polypropylene Mesh Products were in themselves dangerous and defective, particularly when used in the manner intended by Defendants. The polypropylene material used in the Mesh Products was substandard, adulterated and non-medical grade, and was unreasonably subject to oxidative degradation within the body, further exacerbating the adverse reactions caused by the product. The polypropylene Mesh Products were unreasonably susceptible to adhesion, perforation or erosion, fistula formation and bowel strangulation or hernia incarceration, and other injuries.

132. The appropriate treatment for complications associated with the Mesh Products involves additional invasive surgery in an attempt to remove the mesh from the body, thus eliminating any purported benefit that the products were intended to provide to the patient.

133. When the Mesh Products were implanted in Renee Carlson, there were safer feasible alternative designs for hernia mesh products available.

134. The Mesh Products provide no benefit to consumers over other mesh types and increased the risks to patients implanted with these devices.

135. The Mesh Products implanted in Renee Carlson failed to reasonably perform as intended and had to be surgically removed. Thus, further invasive surgery was necessary to repair the very problem that the products were intended to repair, providing only harm and no benefit to her.

136. As a direct and proximate result of the defective and unreasonably dangerous condition of the Mesh Products, Plaintiff Renee Carlson has suffered injuries and damages as summarized in this Complaint including severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including obligations for medical services and expenses, impairment of personal relationships, and other damages.

137. Plaintiff Renee Carlson has suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress.

138. Plaintiff Renee Carlson has also incurred substantial medical bills and has suffered loss of other monies due to the defective Mesh Products that were implanted.

COUNT III: STRICT LIABILITY – FAILURE TO WARN

139. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs with the same force and effect as if more fully set

forth herein.

140. When the Mesh Products were implanted in Plaintiff Renee Carlson's body, the warnings and instructions provided by Defendants for the products were inadequate and defective. There was an unreasonable risk that the product would not perform safely and effectively for the purposes for which they were intended. Defendants failed to design and/or manufacture against such dangers and failed to provide adequate warnings and instructions concerning these risks.

141. Defendants expected and intended the products to reach users such as Plaintiff in the condition in which they were sold.

142. Plaintiff Renee Carlson and/or her physicians were unaware of the defects and dangers of the Mesh Products, and were unaware of the frequency, severity and duration of the risks associated with the products.

143. Defendants' Instructions for Use provided with the products expressly understate and misstate the risks known to be associated specifically with them. Defendants provided no warning to physicians about the risks or increased risks specifically associated with the unique design of the Mesh Products.

144. Defendants' Instructions for Use failed to adequately warn Plaintiff Renee Carlson's physicians of numerous risks, which Defendants knew or should have known were associated with the Mesh Products, including the following: immunologic response, infection, pain, dehiscence, nerve entrapment, nerve damage, encapsulation, rejection, migration, scarification, contraction, erosion through adjacent tissue and viscera, adhesions, bowel obstruction, and tumor or cancer formation.

145. Defendants' Instructions for Use also failed to instruct physicians how much

larger than the hernia defect the products needed to be for an effective repair.

146. As well, the Instructions for Use failed to disclose the extent the Mesh Products would shrink, or that they would even shrink at all.

147. Defendants failed to adequately warn Plaintiff Renee Carlson and/or her physicians about the need for invasive surgical intervention in the event of complications or inform them of the treatment for such complications when they occurred.

148. Defendants failed to adequately warn Plaintiff Renee Carlson and/or her physicians that the surgical removal of the Mesh Products, in the event of complications, would leave the hernia unrepaired and the resulting hernia would be much larger than the original. Thus, more complicated medical treatment would be needed to attempt to repair the same hernia that the failed products were intended to treat.

149. Defendants failed to adequately warn Plaintiff Renee Carlson and/or her physicians that in the event of complications, the Mesh Products are more difficult to fully remove than other feasible hernia meshes that have been available at all material times.

150. Defendants failed to warn Plaintiff Renee Carlson and/or her physicians that as a result of being implanted with the Mesh Products, she would be at a higher risk of infection for the remainder of his life.

151. With respect to the complications listed in Defendants' warnings, they provided no information or warning regarding the frequency, severity and duration of those complications, even though the complications associated with the Mesh Products were more frequent, more severe and longer lasting than those with safer feasible alternative hernia repair treatments.

152. If Plaintiff Renee Carlson and/or her physicians had been properly warned of the defects and dangers of the Mesh Products, and of the frequency, severity and duration of the

risks associated with the products, she would not have consented to allow the products to be implanted, and her physicians would not have implanted them.

153. As a direct and proximate result of the inadequate and defective warnings and instructions, Plaintiff Renee Carlson suffered injuries and damages as summarized in this Complaint including severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including obligations for medical services and expenses, impairment of personal relationships, and other damages.

154. Plaintiff Renee Carlson has suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress.

155. Plaintiff Renee Carlson has also incurred substantial medical bills and has suffered loss of other monies due to the defective Mesh Products that were implanted.

COUNT IV: NEGLIGENCE

156. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs with the same force and effect as if more fully set forth herein.

157. Defendants had a duty to use reasonable care in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, and preparing written instructions and warnings for the Mesh Products, but failed to do so.

158. The negligence of the Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

(a) Manufacturing, producing, promoting, creating, and/or designing the Mesh Products without thoroughly testing them;

(b) Manufacturing, producing, promoting, creating, and/or designing the Mesh

Products without adequately testing them;

(c) Not conducting sufficient testing programs to determine whether or not the Mesh Products were safe for use and/or implantation; in that Defendants herein knew or should have known that the Mesh Products were unsafe and unfit for use and/or implantation by reason of the dangers to its users;

(d) Selling the Mesh Products without making proper and sufficient tests to determine the dangers to its users;

(e) Negligently failing to adequately and correctly warn the Plaintiff, the public, and/or the medical and healthcare profession, and the FDA of the dangers of the Mesh Products;

(f) Negligently advertising and recommending the use of the Mesh Products without sufficient knowledge as to their dangerous and harmful properties;

(g) Negligently representing that the Mesh Products were safe for use for their intended purpose, when, in fact, they were unsafe and harmful;

(h) Negligently representing that the Mesh Products had equivalent safety and efficacy as other types of mesh products used in similar hernia repairs;

(i) Negligently designing the Mesh Products in a manner which were dangerous to their users;

(j) Negligently manufacturing the Mesh Products in a manner which were dangerous to their users;

(k) Negligently assembling the Mesh Products in a manner which were dangerous to their users;

(l) Concealing information from Plaintiff Renee Carlson and/or implanting surgeons

in knowing that the Mesh Products were unsafe and dangerous;

(m) Improperly concealing from and/or misrepresenting information to Plaintiff Renee Carlson and/or healthcare professionals, concerning the severity of risks and dangers of the Mesh Products compared to other hernia mesh devices used in similar hernia repairs.

159. Defendants knew, or in the exercise of reasonable care should have known, that the Mesh Products were defectively and unreasonably designed and/or manufactured and were unreasonably dangerous and likely to injure patients in whom they were implanted. Defendants knew or should have known that Plaintiff Renee Carlson and/or her physicians were unaware of the dangers and defects inherent in the products.

160. Defendants knew or should have known that the MSDS for the polypropylene used to manufacture the Mesh Products prohibited permanently implanting the polypropylene into the human body.

161. Defendants utilized non-medical grade polypropylene.

162. Defendants knew or should have known that the polypropylene component is not inert and would degrade, flake, chip, and disperse throughout the body once implanted.

163. Defendants knew or should have known that polypropylene incites a severe inflammatory response once implanted and continues to incite a severe inflammatory response indefinitely or until removed.

164. Defendants knew or should have known that every piece of polypropylene that flakes off and migrates throughout the body also incites its own chronic inflammatory response wherever it embeds.

165. Defendants knew or should have known that all subsequent operations carry a greater risk of infection after the patient has been implanted with the Mesh Products.

166. As a direct and proximate result of Defendants' negligence in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, and preparing written instructions and warnings for the Mesh Products, Plaintiff Renee Carlson suffered injuries and damages as summarized in this Complaint including severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including obligations for medical services and expenses, impairment of personal relationships, and other damages.

167. Plaintiff Renee Carlson has suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress.

168. Plaintiff Renee Carlson has also incurred substantial medical bills and has suffered loss of other monies due to the defective Mesh Products that were implanted.

COUNT V: BREACH OF IMPLIED WARRANTY

169. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs with the same force and effect as if more fully set forth herein.

170. At all material times, Defendants manufactured, distributed, advertised, promoted, and sold their Mesh Products.

171. At all material times, Defendants intended for their products to be implanted for the purposes and in the manner that Plaintiff Renee Carlson and/or her implanting physicians in fact used them; and Defendants impliedly warranted that the products and their component parts were of merchantable quality, safe and fit for such use, and adequately tested.

172. Defendants were aware that consumers, including Plaintiff Renee Carlson and/or her physicians, would implant their products as directed by the Instructions for Use. Therefore, Plaintiff Renee Carlson was a foreseeable user of Defendants' Mesh Products.

173. Defendants' Mesh Products were expected to reach, and did in fact reach consumers, including Plaintiff Renee Carlson and/or her physicians, without substantial change in the condition in which they were manufactured and sold by Defendants.

174. Defendants breached various implied warranties with respect to the Mesh Products, including the following:

(a) Defendants represented to Plaintiff Renee Carlson and/or her physicians and healthcare providers through labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that their products were safe. But at the same time, they fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the products;

(b) Defendants represented to Plaintiff Renee Carlson and/or her physicians and healthcare providers that their products were safe and/or safer than other alternative procedures and devices. But at the same time, they fraudulently concealed information demonstrating that the products were not safer than alternatives available on the market; and

(c) Defendants represented to Plaintiff Renee Carlson and/or her physicians and healthcare providers that their products were more efficacious than alternative procedures and/or devices. But at the same time, they fraudulently concealed information regarding the true efficacy of the Mesh Products.

175. In reliance upon Defendants' implied warranties, Plaintiff Renee Carlson individually, and/or by and through her physicians, used the Mesh Products as prescribed, and in the foreseeable manner normally intended, recommended, promoted, and marketed by

Defendants.

176. Defendants breached their implied warranties to Plaintiff Renee Carlson in that their products were not of merchantable quality, nor were they safe and fit for their intended use or adequately tested.

177. As a direct and proximate result of Defendants' breaches of the aforementioned implied warranties, Plaintiff Renee Carlson was caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including obligations for medical services and expenses, impairment of personal relationships, and other damages.

178. Plaintiff Renee Carlson has suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress.

179. Plaintiff Renee Carlson has also incurred substantial medical bills and has suffered loss of other monies due to the defective Mesh Products that were implanted.

COUNT VI: BREACH OF EXPRESS WARRANTY

180. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs with the same force and effect as if more fully set forth herein.

181. At all relevant and material times, Defendants manufactured, marketed, sold, distributed and otherwise placed in to the stream of commerce the Mesh Products.

182. In advertising, marketing and otherwise promoting Mesh Products to physicians, hospitals and other healthcare providers, Defendants expressly warranted that their Mesh Products were safe for use and reasonably fit for their intended purposes. In advertising, marketing and otherwise promoting Mesh Products, Defendants' intended that physicians, hospitals and other healthcare providers rely upon their representations regarding safety and

fitness in an effort to induce them to implant Mesh Products in their patients.

183. With respect to the Plaintiff Renee Carlson, Defendants intended that Mesh Products be implanted by her treating surgeons in a reasonable and foreseeable manner in which they were implanted and in accordance with the instructions for use and product specifications provided by Defendants. Plaintiff Renee Carlson was in privity with Defendants.

184. Defendants expressly warranted to physicians, hospitals, other healthcare providers and the general public including Plaintiff Renee Carlson that the Mesh Products were safe and fit for use by consumers, that they were of merchantable quality, that its risks, side effects and potential complications were minimal and comparable to other hernia mesh products, that they was adequately researched and tested, and that they were fit for their intended use. Plaintiff Renee Carlson and her physicians and healthcare providers reasonably relied upon Defendants' express representations and warranties, and consequently, Plaintiff Renee Carlson was implanted with Defendants' Mesh Products.

185. Defendant breached these express warranties because the Mesh Products implanted in Plaintiff Renee Carlson were unreasonably dangerous, defective, and not as Defendants had represented.

186. Defendants breached express representations and warranties made to the Plaintiff Renee Carlson, as well as Plaintiff Renee Carlson's physicians and healthcare providers, with respect to the Mesh Products, including, but not limited to, the following particulars:

A. Defendants represented to Plaintiff Renee Carlson and her physicians and healthcare provides through labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions among other ways that the Defendants' Mesh Products were safe, meanwhile Defendants

fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the Mesh Products.

B. Defendants represented to Plaintiff Renee Carlson and her physicians and healthcare providers that the Defendants' Mesh Products were as safe and/or safer than other alternative procedures and devices on the market, meanwhile Defendants fraudulently concealed information that demonstrated that the Mesh Products were not safer than alternative therapies and products available on the market; and

C. Defendants represented to Plaintiff Renee Carlson and her physicians and healthcare providers that the Defendants' Mesh Products were more efficacious than other alternative procedures, therapies and/or devices, meanwhile Defendants fraudulently concealed information, regarding the true efficacy of the Mesh Products.

187. Defendants' breach of their express warranties resulted in the implantation of unreasonably dangerous and defective products into the Plaintiff Renee Carlson, placing her health and safety in jeopardy

188. At the time of making such express warranties, Defendants knew or should have known that Defendants' Mesh Products do not conform to the express warranties and Defendants' acts were motivated by financial gain while the adverse consequences of Defendants' conduct was outrageous, fraudulent, oppressive, done with malice or gross negligence and evidenced reckless indifference to Plaintiff Renee Carlson's rights, health and safety so as to warrant the imposition of punitive damages.

189. As a direct and proximate result of Defendants' breaches of the aforementioned express warranties, Plaintiff Renee Carlson suffered injuries and damages as summarized in this Complaint including severe personal injuries, pain and suffering, severe emotional distress,

financial or economic loss, including obligations for medical services and expenses, impairment of personal relationships, and other damages.

190. Plaintiff Renee Carlson has suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress. Plaintiff Renee Carlson has also incurred substantial medical bills and has suffered loss of other monies due to the defective Mesh Products that were implanted.

COUNT VII: GROSS NEGLIGENCE

191. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs with the same force and effect as if more fully set forth herein.

192. Defendants' wrongs were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff Renee Carlson, for which the law would allow, and for which Plaintiff will seek at the appropriate time, the imposition of exemplary damages. That is because Defendants' conduct, including the failure to comply with applicable federal standards was specifically intended to cause substantial injury to Plaintiff. Their conduct, when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others; and Defendants were actually, subjectively aware of the risk involved but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or included Defendants' false material representations, with their knowledge that it was false or with reckless disregard as to its truth and as a positive assertion, with the intent that Plaintiff would act upon their representation.

193. Plaintiff Renee Carlson relied on the representation and suffered injury as a

proximate result of this reliance.

194. Plaintiff Renee Carlson therefore will seek to assert claims for exemplary damages at the appropriate time, in an amount within the jurisdictional limits of the Court.

195. Plaintiff Renee Carlson also alleges that Defendants' acts and omissions, whether taken singularly or in combination with others, constitute gross negligence, proximately causing their injuries. In that regard, Plaintiff Renee Carlson will seek exemplary damages in an amount to punish Defendants for their conduct, and to deter other manufacturers from engaging in such misconduct in the future.

196. Plaintiff Renee Carlson has suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress.

197. Plaintiff Renee Carlson has also incurred substantial medical bills and has suffered loss of other monies due to the defective Mesh Products that were implanted.

COUNT VIII: NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

198. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs with the same force and effect as if more fully set forth herein.

199. Defendants carelessly and negligently manufactured, designed, developed, tested, labeled, marketed and sold the Mesh Products to Plaintiff Renee Carlson.

200. Defendants carelessly and negligently concealed the harmful effects of the Mesh Products from Plaintiff Renee Carlson and/or her physicians on multiple occasions and continue to do so to this day.

201. Defendants carelessly and negligently misrepresented the quality, safety and efficacy of the Mesh Products to Plaintiff Renee Carlson and/or her physicians on multiple

occasions and continue to do so to this day.

202. Plaintiff Renee Carlson were directly impacted by Defendants' carelessness and negligence, in that he has sustained, and will continue to sustain, emotional distress, severe physical injuries, economic losses, and other damages as a direct result of the decision to purchase the Mesh Products.

203. Defendants continued to carelessly and negligently misrepresent the quality, safety, efficacy, dangers and contraindications of the Mesh Products to Plaintiff Renee Carlson and/or her physicians, after she sustained emotional distress, severe physical injuries, and economic loss.

204. Defendants continued to carelessly and negligently misrepresent the quality, safety, efficacy, dangers and contraindications of the products to Plaintiff Renee Carlson and/or her physician, knowing that doing so would cause her to suffer additional and continued emotional distress, severe physical injuries, and economic loss.

205. As a proximate result of Defendants' conduct, Plaintiff suffered injuries and damages as summarized in this Complaint including severe and permanent personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including obligations for medical services and expenses, impairment of personal relationships, and other damages.

206. Plaintiff Renee Carlson has suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress.

207. Plaintiff Renee Carlson has also incurred substantial medical bills and has suffered loss of other monies due to the defective Mesh Products that were implanted.

COUNT IX: FRAUDULENT CONCEALMENT

208. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint

contained in each of the foregoing paragraphs with the same force and effect as if more fully set forth herein.

209. At all material times Defendants knew or should have known that the Mesh Products caused large numbers of complications. Moreover, they knew or should have known that the surgical technique and training of implanting physicians was not the cause of the adverse events associated with these devices; the safety and efficacy of the Mesh Products had not been proven with respect to, among other things, the products, their components, their performance, and their method of insertion; and that the products were not safe and effective. Defendants continued to represent that it was safe and effective.

210. Although Defendants knew or should have known about the lack of safety and efficacy of the Mesh Products, they failed to disclose this information to Plaintiff, and/or the treating physicians, and/or the public at large.

211. At all material times, Defendants had the duty and obligation to disclose to Plaintiff Renee Carlson and/or her physicians the true facts concerning the Mesh Products, i.e., their dangerous and defective nature, their lack of efficacy for their purported use and lack of safety in normal use, and their likelihood to cause serious consequences to users, including permanent and debilitating injuries. Defendants concealed these material facts before Plaintiff Renee Carlson was implanted with the Mesh Products.

212. Defendants were under a duty to Plaintiff Renee Carlson to disclose and warn them of the defective nature of the Mesh Products because:

A. Defendants were in a superior position to know the products' true quality, safety, and efficacy;

B. Defendants knowingly made false claims about the products' safety and quality in

documents and marketing materials; and

C. Defendants fraudulently and affirmatively concealed the defective nature of the products from Plaintiff Renee Carlson.

213. The facts Defendants concealed and/or did not disclose to Plaintiff Renee Carlson were material facts that a reasonable person would have considered important in deciding whether to purchase and/or use the Mesh Products.

214. At all material times, Defendants willfully, intentionally, and maliciously concealed facts from Plaintiff Renee Carlson and/or her physician, with the intent to defraud.

215. Defendants intentionally concealed and/or failed to disclose the true defective nature of the Mesh Products so that Plaintiff Renee Carlson would request and purchase the product; and his healthcare providers would dispense, prescribe, and recommend the product. Plaintiff justifiably acted or relied upon the concealed and/or non-disclosed facts to their detriment.

216. At all material times, neither Plaintiff Renee Carlson nor her physician were aware of the facts.

217. Had they been so aware, they would not have reasonably relied upon the representations of safety and efficacy and would not have utilized the Mesh Products. Defendants' failure to disclose this information was a substantial factor in Plaintiff Renee Carlson's physician's selection of the Mesh Products. The failure to disclose also resulted in the provision of incorrect and incomplete information to Plaintiff Renee Carlson as a patient.

218. As a direct and proximate result of this conduct, Plaintiff Renee Carlson suffered injuries and damages as summarized in this Complaint including severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including obligations for

medical services and expenses, impairment of personal relationships, and other damages.

219. Plaintiff Renee Carlson has suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress.

220. Plaintiff Renee Carlson has also incurred substantial medical bills and has suffered loss of other monies due to the defective Mesh Products that were implanted.

COUNT X: NEGLIGENT MISREPRESENTATION

221. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs with the same force and effect as if more fully set forth herein.

222. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff Renee Carlson and/or the public, that the Mesh Products had not been adequately tested and found to be a safe and effective treatment. Defendants' representations were in fact false.

223. Defendants failed to exercise ordinary care in their representations concerning the Mesh Products while involved in the manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce of the products, because they negligently misrepresented the products' risk of unreasonable and dangerous adverse side effects.

224. Defendants breached their duty by representing to Plaintiff Renee Carlson and/or her physicians, and/or the medical community that the Mesh Products have no serious side effects different from older generations of similar products or procedures.

225. As a foreseeable, direct, and proximate result of Defendants' negligent misrepresentations, they knew, or had reason to know, that the Mesh Products had been insufficiently tested, or had not been tested at all; and that the products lacked adequate and

accurate warnings, and created a high risk—and/or higher than acceptable or reported and represented risk—of adverse side effects, including pain, nerve entrapment, nerve damage, graft rejection, graft migration, organ damage, complex seroma, fistula, sinus tract formation, dense adhesions, delayed wound closure, infection, sepsis, and death.

226. As a direct and proximate result of Defendants' conduct, Plaintiff Renee Carlson suffered injuries and damages as summarized in this Complaint including severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including obligations for medical services and expenses, impairment of personal relationships, and other damages.

227. Plaintiff Renee Carlson has suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress.

228. Plaintiff Renee Carlson has also incurred substantial medical bills and has suffered loss of other monies due to the defective Mesh Products that were implanted.

PUNITIVE DAMAGES

229. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs with the same force and effect as if more fully set forth herein.

230. Defendants failed to adequately test and study the Mesh Products to determine and ensure that the products were safe and effective prior to releasing them for sale for permanent human implantation; and Defendants continued to manufacture and sell the products after obtaining knowledge and information that they was defective and unreasonably unsafe.

231. Defendants developed, designed and sold the products, and continue to do so, because they had a significantly higher profit margin than safer hernia repair products.

Defendants were aware of the probable consequences of implantation of the dangerous and defective Mesh Products, including the risk of failure and serious injury, such as that suffered by Plaintiff Renee Carlson.

232. At all material times, Defendants knew or should have known that the Mesh Products were inherently more dangerous with respect to the risk of foreign body response, allergic reaction, rejection, infection, failure, erosion, nerve entrapment, nerve damage, pain and suffering, organ perforation, dense adhesions, tumor or cancer formation, loss of life's enjoyment, remedial surgeries and treatments to attempt to cure the conditions related to use of the product, as well as the other severe and personal injuries that are permanent and lasting.

233. Defendants' misrepresentations include knowingly withholding material information from the medical community and/or the public, including Plaintiff, concerning the safety and efficacy of the Mesh Products, depriving Plaintiff Renee Carlson and/or her implanting physicians of vitally necessary information with which to make a fully informed decision about whether to use the products.

234. At all material times, Defendants knew and recklessly and/or intentionally disregarded the fact that the Mesh Products can cause debilitating and potentially life-threatening side effects with greater frequency than safer alternative methods, products, procedures, and/or treatment.

235. At all material times, Defendants knew and recklessly and/or intentionally disregarded the fact that the Mesh Products can cause debilitating and potentially life-threatening side effects with greater frequency than safer alternative products and/or methods of treatment, and recklessly failed to advise the medical community and/or the general public, including Plaintiff, of those facts.

236. At all material times, Defendants intentionally misstated and misrepresented data; and continue to misrepresent data so as to minimize the perceived risk of injuries and the rate of complications caused by the Mesh Products.

237. Notwithstanding the foregoing and the growing body of knowledge and information regarding the true defective nature of the Mesh Products, and its increased risk of side effects and serious complications, Defendants continue to aggressively market the products to the medical community and/or to consumers without disclosing the true risk of such complications.

238. When Plaintiff Renee Carlson was implanted with the Mesh Products, and since then, Defendants have known the products were defective and unreasonably dangerous. But they continued to manufacture, produce, assemble, market, distribute, and sell the products so as to maximize sales and profits at the expense of the health and safety of the public in a conscious, reckless and/or intentional disregard of the likely and foreseeable harm caused by the Mesh Products to members of the public, including Plaintiff Renee Carlson.

239. At all material times, Defendants have concealed and/or failed to disclose to the public the serious risks and the potential complications associated with the Mesh Products, in order to ensure continued and increased sales and profits, to the detriment of the public, including Plaintiff Renee Carlson.

240. Defendants' conduct, acts and omissions are of such character and nature so as to entitle Plaintiff to an award of punitive damages in accordance with applicable law. Defendants' conduct shows willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care raising the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages.

241. WHEREFORE, Plaintiffs demand judgment against Defendants, individually, jointly, and severally, and in the alternative requests compensatory damages, punitive damages or enhanced compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

LOSS OF CONSORTIUM

242. Plaintiffs repeat, reiterate, and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

243. Plaintiff Gregory Carlson was and is the lawful spouse of Plaintiff Renee Carlson and in such capacity, was and is entitled to the comfort, enjoyment, society, and services of his spouse.

244. As a direct and proximate result of the foregoing allegations, Plaintiff Gregory Carlson was deprived of the comfort, enjoyment, society, and services of his spouse, has suffered and will continue to suffer economic loss, and otherwise has been emotionally and economically injured. Plaintiff Gregory Carlson's injuries and damages are permanent and will continue into the future.

245. Accordingly, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages or enhanced compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

PRAYER FOR RELIEF

Plaintiffs demand judgment against Defendants, and pray for the following relief in accordance with applicable law and equity:

i. Compensatory damages to Plaintiffs for past, present, and future damages, including but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiffs, permanent impairment, mental pain and suffering, loss of enjoyment of life, health and medical care costs, economic damages, together with interest and costs as provided by law;

ii. Restitution and disgorgement of profits;

iii. Punitive damages;

iv. Reasonable attorneys' fees as provided by law;

v. Past and future cost of all proceedings;

vi. All ascertainable economic damages;

vii. Prejudgment interest on all damages as allowed by law;

viii. Loss of Consortium; and

ix. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury on all issues so triable.

Dated: June 14, 2021

Respectfully submitted,

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